DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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December 29, 2005

Davis S. Caskey
ECR Pharmaceuticals
3969 Deep Rock Road
Richmond, Virginia 23233

Re: Docket No. 2005P-0244/CP1

Dear Mr. Caskey:

This letter responds to your citizen petition, dated June 16, 2005, requesting that the Food and Drug Administration (FDA) determine whether Decadron (dexamethasone) 1.5 mg tablets were withdrawn from sale for reasons of safety or effectiveness, and whether an abbreviated new drug application (ANDA) may be submitted for approval to market this dose strength.

FDA has reviewed its records and determined that Decadron (dexamethasone) 1.5 mg tablets were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Decadron (dexamethasone) 1.5 mg tablets, in the *Discontinued Drug Product List* section of *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. Should you have any questions, please do not hesitate to contact me at 301-594-2041.

Sincerely,

Janice L. Weiner

Janice L. Weiner
Division of Regulatory Policy II
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

2005P-0244

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